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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ryszard M. Lec

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,567	Applicant(s) LEC ET AL.	
	Examiner KAREN E. TOTH	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-51 is/are pending in the application.
- 4a) Of the above claim(s) 17-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 33-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 33-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant uses the phrase “biological sensing media”, but this term is not defined in the specification or claims of the present application; additionally, the term is not even *present* in the specification or original set of claims. It appears that applicant is attempting to identify the component labeled as “bio-sensing element” in figure 1; for examination purposes, the claims will be treated as such.

The Examiner notes that Applicant has attempted to show that this connection may be inferred based on a passage in the specification. This is not sufficient to overcome the rejection, as there is still no direct connection between the language in the claims and the language in the specification. The Examiner suggests amending the claims to match the language of the invention disclosed in the specification.

Claim Rejections - 35 USC § 102

3. Claims 33, 37, 38, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Burke (US Patent Application Publication 2004/0157337).

Regarding claim 33, Burke discloses a blood analysis device comprising a transducer element (paragraphs [0062], [0065]), a biological sensing media in communication with the transducer element (paragraph [0055]), a signal driver in communication with the transducer element that applies a varying signal to the transducer (paragraphs [0062], [0065]), an inlet port to direct blood to the transducer (paragraph [0072]), and a signal processor in communication with the transducer that measures a response of the blood to the signal and determines a blood characteristic as a function of the measured response (paragraphs [0068], [0071]).

Regarding claims 37 and 38, Burke further discloses varying the frequency between 1 KHz and 10 GHz (paragraphs [0062]-[0065]).

Regarding claim 43, Burke further discloses the device being self-administered (paragraph [0054]).

4. Claims 33, 36, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Freiherr Von Der Goltz (US Patent 7223365).

Regarding claim 33, Freiherr Von Der Goltz discloses a blood analysis device comprising a transducer element (column 3, lines 2-17; element 4), biological sensing media in communication with the transducer (column 2, lines 49-53), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 17, 18), an inlet port for delivering blood to the transducer element (element 5), and a signal processor in connection with the transducer for determining a blood characteristic from the blood's response to the varying signal (elements 9, 18).

Regarding claim 36, Von Der Goltz further discloses a bioactive material on the transducer element (column 11, lines 50-62).

Regarding claim 42, Freiherr Von Der Goltz further discloses a catheter (element 57).

5. Claims 33-35, 37, 39, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Grzegorzewski (US Patent 5494639).

Regarding claim 33, Grzegorzewski discloses a blood analysis device comprising a transducer element (elements 14), biological sensing media in communication with the transducer (element 13), a signal driver in communication with the transducer for applying a signal to the transducer and varying it (element 8), an inlet port to direct blood to the transducer element (element 11), and a signal processor in communication with the transducer that determines a blood characteristic from the blood's response to the applied signal (element 52).

Regarding claim 34, Grzegorzewski discloses the transducer as an electrostrictive element (column 3, lines 39-61).

Regarding claim 35, Grzegorzewski further discloses the transducer including a plurality of sensors (electrodes 14).

Regarding claim 37, Grzegorzewski discloses varying an applied frequency (column 3, lines 43-53; column 6, lines 8-10). Regarding claim 39, the Examiner notes that there are no alternatives to individual, sequential, and simultaneous delivery of a

signal, and Grzegorewski's signal therefore inherently is delivered via one of these options.

Regarding claim 47, Grzegorzewski discloses a bulk bioactive material (element 13; column 3, lines 29-37).

Claim Rejections - 35 USC § 103

6. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Der Goltz in view of Jina (US Patent 6673622).

Von Der Goltz discloses all the elements of the claimed invention, as described above, except for the device comprising data storage, processing, and transmission of physiological characteristics and providing information to a patient. Jina teaches a blood characteristic analysis system comprising data storage, processing, and transmission, including storing blood data and providing information to a patient via a display (column 6 line 30 to column 7 line 23), in order to effectively analyze and use the gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Von Der Goltz with data storage, processing, and transmission, and display of information, as taught by Jina, in order to effectively analyze and use the gathered data.

7. Claims 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Von Der Goltz in view of Stiene (US Patent Application Publication 2004/0072357).

Regarding claims 48 and 51, Von Der Goltz discloses all the elements of the claimed invention, as described above, except for the device comprising data storage, processing, and transmission, and wired and wireless communication. Stiene teaches a blood characteristic analysis system comprising data processing, storage, and transmission, including wired and wireless communication between the device, a patient, and a health center (paragraphs [0044], [0055]-[0066], [0078], [0115]), in order to facilitate analysis of gathered data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Von Der Goltz with data processing, storage, and transmission, as well as wired and wireless communication, as taught by Stiene, in order to facilitate data analysis.

8. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Von Der Goltz.

The Examiner notes that Von Der Goltz does not expressly disclose the effect generated by the transducer traveling between 1 nm and 1 cm into the blood from the transducer's surface. However, the distance the signal travels is a function of the sample volume, as well as the type of signal being applied and the strength and frequency of that signal. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the device such that the transducer's effect would travel between 1 nm and 1 cm from its surface.

9. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Corey (US Patent Application Publication 2004/0054283).

Burke discloses all the elements of the claimed invention, as described above, except for the frequencies including a resonant, antiresonant, harmonic, or anharmonic frequency. Corey teaches analyzing blood characteristics at a resonant frequency (paragraph [0113]), in order to accurately calculate hematocrit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the system of Burke at a resonant frequency, as taught by Corey, in order to obtain accurate measurements.

Allowable Subject Matter

10. Claims 44-46 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments filed 17 March 2008 have been fully considered but they are not persuasive.

Regarding Applicant's argument that Grzegorzewski does not disclose a signal driver that applies a varying signal value to the transducer, the Examiner disagrees. The vibrating piezoelectric element applies a varying signal to the electrodes, which are in turn connected to a signal processor.

Regarding Applicant's argument that Von Der Goltz does not apply a signal and measure a blood characteristic in response to the signal, the Examiner disagrees. Von Der Goltz clearly applies a varying pressure wave to a blood sample; the resulting change in pressure and flow velocity is measured to determine the characteristics of the blood (column 9, lines 31-47).

The Examiner also notes that, though Applicant disliked addressing a plurality of art rejections, each individual prior art addressed a different set of dependent claims.

Applicant's arguments with respect to Jina and Stiene have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 6524861 to Anderson, and US Patent Application Publication 2004/0214337 to Kautzky, which disclose similar inventions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

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